

AMENDMENTS TO THE CLAIMS

The following listing of claims will replace all prior versions and listings of claims in the application.

LISTING OF CLAIMS

1. (Currently Amended) An image guided navigation system for guiding an instrument through a region of a patient, said image guided navigation system comprising:

an anatomical gating device that senses a physiological event;

an imaging device that captures image data of the region of the patient in response to said physiological event;

a tracking device that tracks the position of the instrument in the region of the patient;

a controller in communication with said anatomical gating device, said imaging device and said tracking device to register said image data with the region of the patient in response to said physiological event, said controller further ~~superimposes an icon representing the instrument onto the image data of the region of the patient, based upon the position tracked by said tracking device, and said controller provides an estimated optimized site to navigate the instrument with the estimated optimized site represented as a separate icon superimposed onto the image data~~ operable to register a 3-D model image to the image data and provide navigation and information of a possible path to direct the instrument through the region of the patient to an estimated optimized target site, wherein the estimated optimized target site can be identified on the 3-D model image along with a real time view of an icon representing the instrument

moving toward the estimated optimized target site, wherein the estimated optimized target site is based at least in part on a statistical map that suggests where instrument placement should take place depending on the pathology of the patient; and

a display that displays the image data of the region of the patient with the superimposed icon of the instrument and the superimposed icon of the estimated optimized target site, such that a user knows where the estimated optimized target site is on the 3-D map or display and can simply navigate the instrument toward this estimated optimized target site.

2. (Original) The image guided navigation system as defined in Claim 1 wherein said imaging device is operable to synchronize image data in the region of the patient in response to said physiological event by capturing an image in response to said physiological event.

3. (Original) The image guided navigation system as defined in Claim 1 wherein said imaging device is operable to synchronize image data in the region of the patient in response to said physiological event by sampling image data from an acquired image in response to said physiological event.

4. (Original) The image guided navigation system as defined in Claim 1 wherein said imaging device is selected from a group of 2D, 3D or 4D imaging devices comprising a C-arm fluoroscopic imager, a magnetic resonance imager (MRI), a computed tomography (CT) imager, a positron emission tomography (PET) imager, an

isocentric fluoroscopy imager, a bi-plane fluoroscopy imager, an ultrasound imager, a multi-slice computed tomography (MSCT) imager, a high-frequency ultrasound (HIFU) imager, an optical coherence tomography (OCT) imager, an intra-vascular ultrasound imager (IVUS), an ultrasound imager, an intra-operative CT imager, an intra-operative MRI imager, a single photon emission computer tomography (SPECT) imager, and a combination thereof.

5. (Original) The image guided navigation system as defined in Claim 1 wherein said tracking device is selected from a group comprising an electromagnetic tracking device, an optical tracking device, a conductive tracking device, a fiberoptic tracking device, and a combination thereof.

6. (Original) The image guided navigation system as defined in Claim 1 wherein said imaging device is a C-arm fluoroscopic x-ray imaging device operable to generate multiple two-dimensional images of the region of the patient.

7. (Original) The image guided navigation system as defined in Claim 1 wherein said tracking device is an electromagnetic tracking device having a transmitter coil array operable to generate an electromagnetic field in the region of the patient and a plurality of sensors associated with the instrument operable to sense the electromagnetic field.

8. (Original) The image guided navigation system as defined in Claim 1 wherein said instrument is operable to deliver a therapy to the patient.

9. (Original) The image guided navigation system as defined in Claim 8 wherein the therapy is selected from a group comprising lead placement, drug delivery, gene delivery, cell delivery, ablation, and a combination thereof.

10. (Canceled)

11. (Original) The image guided navigation system as defined in Claim 1 wherein said controller is further operable to register said image data with the region of the patient using a registration technique selected from at least one of point registration, surface registration, path registration, 2D to 3D registration 3D to 3D registration and 4D to 4D registration.

12. (Original) The image guided navigation system as defined in Claim 1 wherein the position of the instrument is detected at said physiological event and said imaging device captures the image data at said physiological event, such that the position of the instrument is synched with the captured image data.

13. (Original) The image guided navigation system as defined in Claim 1 wherein said instrument is selected from a group comprising a catheter, a guide wire, a stylet, an insert, a needle and a combination thereof.

14. (Original) The image guided navigation system as defined in Claim 1 wherein said instrument includes at least one sensor selected from a group comprising electrical sensor, a pressure sensor, electro physiological (EP) sensor, a hemo-dynamic sensor, an impedance sensor, and a temperature sensor.

15. (Currently Amended) The image guided navigation system as defined in Claim 14 wherein said signal from one of said sensors is also utilized to provide ~~[[an]]~~ the estimated optimized target site to ~~navigate the instrument to which the~~ instrument can be navigated.

16. (Original) The image guided navigation system as defined in Claim 1 wherein said instrument is a guided biopsy catheter operable to be tracked by said tracking device through the region of the patient.

17. (Original) The image guided navigation system as defined in Claim 1 wherein said instrument delivers a therapy in response to said sensed physiological event from said anatomic gating device.

18. (Original) The image guided navigation system as defined in Claim 17 wherein said therapy is selected from a group comprising drug delivery, gene delivery, cell delivery, ablation, lead delivery, stent delivery, implant delivery, and a combination thereof.

19. (Original) The image guided navigation system as defined in Claim 17 wherein said gated delivery includes simultaneous stimulation of the therapy.

20. (Original) The image guided navigation system as defined in Claim 1 wherein said instrument is guided through a cerebrospinal fluid tree or vascular tree of the patient.

21. (Original) The image guided navigation system as defined in Claim 1 wherein said imaging device is an ultrasound imaging device located outside of the patient, wherein the image data generates a virtual view from the instrument.

22. (Currently Amended) An image guided navigation system for navigating to an optimized site in the patient using image data, said image guided navigation system comprising:

an instrument operable to be navigated to the optimized site, wherein the optimized site is an optimized lead placement site for coupling a cardiac lead to a coronary sinus region;

a tracking device attached to said instrument and operable to be used to track the position of the instrument in the patient;

at least one sensor attached to said instrument and operable to sense a physiological parameter in the patient;

a controller that tracks the position of the instrument with said tracking device and receives the sensed physiological parameter from said sensor, said controller further estimates the optimized site based at least in part on the sensed physiological parameter and on the position of the instrument and superimposes an icon representing the location of the optimized site, an icon representing a path through the anatomy to the optimized site, and an icon representing the instrument, ~~based on the sensed physiological parameter and on the position of the instrument;~~

a display that displays the icon of the estimated optimized site, the icon of the path to the optimized site, and the icon representing the instrument in the patient;
and

~~wherein the optimized site is an optimized lead placement site for coupling a cardiac lead to a coronary sinus region.~~

23. (Original) The image guided navigation system as defined in Claim 22 wherein said instrument is selected from a group comprising a catheter, a guide wire, a stylet, an insert, a needle and a combination thereof.

24. (Original) The image guided navigation system as defined in Claim 23 wherein said tracking device is selected from at least one of an electromagnetic, optical, acoustic, and conductive tracking devices.

25. (Original) The image guided navigation system as defined in Claim 22 wherein said at least one sensor is an ultrasound transducer operable to generate a Doppler effect to provide hemo-dynamic physiological parameters.

26. (Original) The image guided navigation system as defined in Claim 22 wherein said at least one sensor is selected from at least one of a temperature sensor, pressure sensor, hemo-dynamic sensor, EP sensor, impedance sensor, accelerometer, tissue sensor, spectroscopy sensor and a combination thereof.

27. (Currently Amended) The image guided navigation system as defined in Claim 22 wherein said controller is further operable to ~~generate an atlas map based on previously acquired optimized sites~~ register an atlas model image to the image data and provide navigation and information of a possible path to direct the instrument through the region of the patient to the optimized site, wherein the optimized site can be identified on the atlas model image along with a real time view of an icon

representing the instrument moving toward the optimized site, wherein the optimized site is based at least in part on a statistical map that suggests where instrument placement should take place depending on the pathology of the patient.

28. (Currently Amended) The image guided navigation system as defined in Claim 27 wherein said atlas ~~[[map]]~~ model image is further utilized to estimate the optimized site in addition to said sensed physiological parameter.

29. (Canceled)

30. (Original) The image guided navigation system as defined in Claim 22 wherein said controller is further operable to register said image data with the patient using a registration technique selected from at least one of point registration, surface registration, path registration, 2D to 3D registration, 3D to 3D registration and 4D to 4D registration.

31. (Original) The image guided navigation system as defined in Claim 22 further comprising an anatomic gating device operable to sense a physiological event wherein said image data is gated to said physiological event and wherein registration by said controller is gated to said physiological event.

32. (Original) The image guided navigation system as defined in Claim 22 wherein said instrument is a guided biopsy catheter.

33. (Original) The image guided navigation system as defined in Claim 22 further comprising a tracking system operable to track said instrument by tracking said tracking device attached to said instrument.

34. (Original) The image guided navigation system as defined in Claim 33 wherein said tracking system is selected from a group comprising an electromagnetic tracking system, an optical tracking device, a conductive tracking system, a fiberoptic tracking system, and a combination thereof.

35. - 43. (Canceled)

44. (Currently Amended) A method for image guiding an instrument in a region of a patient, said method comprising:

- tracking an instrument within an anatomy of the patient with a tracking system;
- identifying a physiological event;
- ~~capturing a first image data in response to the physiological event from~~ outside the patient with an ultrasound probe;
- capturing a second image data from outside the patient with a second image modality different from the ultrasound probe;
- registering the captured first image data and the second image data to the patient ~~and the tracked instrument during the physiological event~~;
- displaying ~~[[the]]~~ a location of the instrument on ~~[[the]]~~ at least one of the first image data or the second image data of the region of the patient by superimposing an icon of the instrument on the image data; ~~[[and]]~~
- calibrating a field of view of the tracked instrument in a coordinate system of the tracking system;
- generating virtual viewpoint image data from at least one of the captured first image data or second image data to be from a virtual viewpoint of the tracked instrument; and
- displaying the ~~ultrasound~~ the generated virtual viewpoint image data from ~~[[a]]~~ the virtual viewpoint of the tracked instrument within the anatomy with the other of the first image data or the second image data.

45. (Original) The method as defined in Claim 44 further comprising delivering a treatment with the instrument when the instrument reaches a desired location.

46. (Original) The method as defined in Claim 44 further comprising navigating the instrument through the region of the patient.

47. (Original) The method as defined in Claim 44 further comprising sensing a physiological parameter with the instrument.

48. (Original) The method as defined in Claim 47 wherein sensing of the physiological parameter is during the physiological event.

49. (Original) The method as defined in Claim 48 wherein the physiological event is a heartbeat.

50. (Canceled)

51. (Original) The method as defined in Claim 44 further comprising delivering a therapy and a stimulus to the therapy.

52. (Currently Amended) A method for image guiding an instrument to an optimized site in a patient, said method comprising:

- navigating the instrument in the patient;
- detecting a location of the instrument;
- sensing a physiological parameter with the instrument;
- capturing image data of the patient in response to a physiological event;
- automatically determining with a controller an optimized site to navigate the instrument to;
- delivering a cardiac lead to the optimized site; and
- superimposing an icon of the optimized site and an icon of the location of the catheter on the image data.

53. - 54. (Canceled)

55. (Original) The method as defined in Claim 52 further comprising delivering a therapy with the instrument at the optimized site.

56. (Original) The method as defined in Claim 55 further comprising delivering the therapy during a physiological event.

57. (Previously Presented) The method as defined in Claim 55 further comprising delivering the lead to a coronary sinus region.

58. (Original) The method as defined in Claim 52 wherein the physiological parameter is at least one of a pressure, temperature, hemo-dynamic, acceleration, electrophysiological, and a combination thereof.

59. (Original) The method as defined in Claim 52 further comprising registering the location of the instrument with pre-acquired images using at least one of point registration, surface registration and path registration.

60. (Original) The method as defined in Claim 59 further comprising registering during an identified physiological event.

61. (Original) The method as defined in Claim 60 wherein the physiological event is a portion of the heartbeat.

62. (Previously Presented) The method as defined in Claim 52 further comprising delivering the cardiac lead through a catheter to the coronary sinus region of the patient.

63. (Currently Amended) An image guided navigation system for guiding an instrument through a region of a patient, said image guided navigation system comprising:

an anatomical gating device operable to sense a physiological event;

an imaging device operable to capture image data of the region of the patient in response to the physiological event;

a tracking device operable to track the position of the instrument in the region of the patient;

a controller in communication with said anatomical gating device, said imaging device and said tracking device, wherein said controller operates to:

~~and operable to~~ (i) synchronize captured image data of the region of the patient in response to a physiological event,

~~said controller further operable to~~ (ii) register said synchronized image data of the region of the patient in response to said physiological event,

~~and to~~ (iii) provide an estimated optimized site to navigate the instrument to, and

~~said controller further operable to~~ (iv) (a) superimpose an icon representing the instrument on to the image data of the region of the patient, based upon the position tracked by said tracking device, (b) to superimpose an icon of the estimated optimized site on to the image data of the region of the patient, and (c) to superimpose a path for the instrument to navigate to reach the estimated optimized site onto the image data; and

a display operable to display the image data of the region of the patient with the superimposed ~~icon of the instrument~~ icons.

64. (Original) The image guided navigation system as defined in Claim 63 wherein said tracking device is selected from a group comprising an electromagnetic tracking device, an optical tracking device, a conductive tracking device, a fiberoptic tracking device, and a combination thereof.

65. (Canceled)

66. (Original) The image guided navigation system as defined in Claim 63 wherein said instrument delivers a therapy in response to said sensed physiological event from said anatomic gating device.

67. (Previously Presented) The image guided navigation system of Claim 1 wherein said physiological event comprises a particular point or time in a cardiac cycle.

68. (Currently Amended) The image guided navigation system of Claim 1

An image guided navigation system for guiding an instrument through a region of a patient, said image guided navigation system comprising:

an anatomical gating device that senses a physiological event;

an imaging device that captures image data of the region of the patient in response to said physiological event;

a tracking device that tracks the position of the instrument in the region of the patient;

a controller in communication with said anatomical gating device, said imaging device and said tracking device to register said image data with the region of the patient in response to said physiological event, said controller further superimposes an icon representing the instrument onto the image data of the region of the patient, based upon the position tracked by said tracking device, and said controller provides an estimated optimized site to navigate the instrument with the estimated optimized site represented as a separate icon superimposed onto the image data; and

a display that displays the image data of the region of the patient with the superimposed icon of the instrument and the superimposed icon of the estimated optimized site;

wherein the controller determines if the instrument can navigate to the estimated optimized site of the anatomy based on physical instrument information and an analysis of the image data and the display displays a notification to select a different instrument if the selected instrument cannot navigate the anatomy.

69. (New) The image guided navigation system as defined in Claim 1, wherein the information regarding the possible path includes an icon superimposed on the image data.

70. (New) The image guided navigation system as defined in Claim 69, further comprising:

a switch to alter the length of the icon superimposed on the image data.

71. (New) The method of Claim 52, wherein automatically determining with a controller an optimized site includes the controller:

receiving the detected the location of the instrument;

receiving the sensed physiological parameter;

estimating the optimized site based at least in part on the sensed physiological parameter and on the detected location of the instrument; and

superimposing an icon representing the location of the optimized site.

72. (New) The method of Claim 52, wherein automatically determining with a controller an optimized site includes the controller:

registering an atlas model image to the captured image data;

receiving the pathology of the patient and a statistical map; and

providing navigation and path information to direct the instrument through the patient to the optimized site, wherein the optimized site can be identified on the atlas model image.

73. (New) The method of Claim 52, wherein automatically determining with a controller an optimized site includes the controller:

receiving the detected the location of the instrument;

receiving the sensed physiological parameter;

registering an atlas model image to the captured image data;

receiving the pathology of the patient and a statistical map; and

providing navigation and possible path information to direct the instrument through the patient to the optimized site, wherein the optimized site can be identified on the atlas model image;

wherein the optimized site is based at least in part on all of the received detected location of the instrument, the received sensed physiological parameter, and the received pathology of the patient and statistical map.

74. (New) The image guided navigation system as defined in Claim 63 wherein the controller is further operates to register a 3-D model image to the image data and provide navigation and path information to direct the instrument through the region of the patient to the estimated optimized site, wherein the estimated optimized site can be identified on the 3-D model image along with a real time view of the icon representing the instrument moving toward the estimated optimized site, wherein the

estimated optimized site is based at least in part on a statistical map that suggests where instrument placement should take place depending on the pathology of the patient.

75. (New) The method of Claim 44, further comprising:
- identifying a physiological event of the patient;
 - capturing image data, in response to the physiological event, from an exterior of the patient with the ultrasound probe; and
 - wherein registering further includes registering the captured image data to the tracked instrument during the physiological event.